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510(K) SUMMARY

JUL 20 2011

ARTHROCARE CORPORATION
SPEEDFIX SUTURE SYSTEM

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-3523
Establishment Registration No.:	2951580
Contact Person:	Laura N. Kasperowicz Sr. Manager, Regulatory Affairs
Date Prepared:	May 19, 2011

Device Description

Model Name:	SpeedFix Suture System
Generic/Common Name:	Bone Anchor, Fastener, Fixation, Soft Tissue
Classification Name:	Fastener, Fixation, Nondegradeable, Soft Tissue
Device Classification:	Class II per 21 CFR 888.3040, Product code: MBI
Model Name:	Drill, 3.0mm
Generic/Common Name:	Bone Drill
Model Name:	PathFinder® Obturator
Generic/Common Name:	Bone Hole Locator
Model Name:	Sharp-Tipped Obturator
Generic/Common Name:	Bone Hole Locator
Model Name:	Drill Guide, 3.5mm High Visibility
Generic/Common Name:	Drill Guide
Model Name:	Drill Guide, 3.5mm Low Profile
Generic/Common Name:	Drill Guide

Predicate Devices

SpeedFix Suture Implant	K101437 (October 29, 2010)

Product Description

The SpeedFix Suture System is a bone anchor system with inserter handle designed for specific indications in arthroscopic and orthopedic procedures.

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Indications For Use

The SpeedFix Suture Implant with inserter is indicated for use in fixation of soft tissue to bone. Examples of such procedures include:
Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis and deltoid repair
Ankle: Lateral instability, medial instability, Achilles tendon repair/reconstruction and midfoot reconstruction
Foot: Hallux valgus reconstruction
Elbow: Tennis elbow repair, biceps tendon attachment
Knee: Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

Substantial Equivalence

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The SpeedFix Suture Implant design and technology is substantially equivalent to the existing SpeedFix Suture Implant [K101437]. Side by side comparison bench testing was performed on the proposed and predicate device per the US FDA Guidance Document for Testing Bone Anchors. The differences between the SpeedFix and the predicate device do not raise any questions regarding the safety and effectiveness of the implant. Furthermore, the materials are well characterized and have been used in predicate devices with similar indications. The proposed device, as designed, is as safe and effective as predicate devices.

Summary and Reason for 510k Notification

The purpose of this 510(k) is to notify the Food and Drug Administration of a proposed modification to an existing product. The proposed device, the SpeedFix Suture Implant is substantially equivalent to the SpeedFix Suture Implant originally cleared under K101437.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ArthroCare Corp.
ArthorCare – The Opus Collection (Formerly Opus Medical)
% Laura N. Kasperowicz
Sr. Manager, Regulatory Affairs
15285 Alton Parkway
Suite 200
Irvine, CA 92618

JUL 20 2011

Re: K111399
Trade/Device Name: SpeedFix™ Suture System
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 5, 2011
Received: July 6, 2011

Dear Ms. Kasperowicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K111399 (pg 1/1)

Device Name: SpeedFix™ Suture System

Indications for Use:

The SpeedFix Suture Implant is indicated for use in fixation of soft tissue to bone. Examples of such procedures include:
Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis and deltoid repair
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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	NO

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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